

Remarks

The following remarks are in response to the Office Communication.

Summary of Claim Status

In the application, Claims 21-24 are pending. Claims 1-20 and 25 were canceled previously.

Claims 21-24 presently stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention, and 35 U.S.C. § 102(e) as being anticipated by Lazar et al. (US 2004/0132101).

Rejection under 35 U.S.C. § 112, second paragraph

Claims 21-24 presently stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. More specifically, the Examiner alleges that Claims 21-24 are indefinite in that they only describe the number of amino acid residue positions without reciting the numbering system.

The standard for indefiniteness is whether “one skilled in the art would understand the bounds of the claim when read in light of the specification.” Exxon Research and Engineering Co. v. United States, 265 F.3d 1371, 1375, 60 USPQ2d 1272 (Fed. Cir. 2001). The Applicant respectfully submits that one skilled in the art would understand the bounds of Claims 21-24 when read in light of the specification. Therefore, Applicant asserts that the Examiner’s rejection of Claims 21-24 is improper. However, in order to expedite prosecution of the instant application, Applicant has amended Claim 21 to incorporate the “EU index format as in Kabat” as the numbering system defining the position of the amino acid residues. Applicant respectfully requests entry of the amendment to the claims. Support for the amendment to the claims can be found, for example, at paragraph 147 of the application as published in US 2008/0089892. Therefore, no new matter is presented by the present amendment.

Rejection under 35 U.S.C. 102(e)

Claims 21-24 presently stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lazar et al. (US 2004/0132101) as well. This rejection is respectfully traversed also. Reconsideration of the rejection and withdrawal thereof are requested on the following basis.

It is axiomatic that in order for a reference to anticipate a claim, it must show each and every feature of the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983). Furthermore, the identical invention must be shown in as complete detail as is contained in the patent claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Stating its intention to clarify the law of anticipation, the CAFC recently held that “unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIN, Inc. v. Verisign, Inc., et al.*, Fed. Cir., No. 2007-1565, pp. 17-18, 10/20/2008. The Applicant submits that the present anticipation rejection is improper because the Lazar et al. reference fails to teach each and every feature of the present claims arranged as recited therein, in as complete detail as is contained in the present claims. The present claims are directed to monoclonal antibodies comprising a variant of a parent human IgG Fc region, wherein the variant consists of a parent human Fc region substituted at **position 247** according to the EU index format as in Kabat with an amino acid selected from the group consisting of **leucine and isoleucine (emphasis added)**. The Lazar et al. reference does not teach a leucine or an isoleucine substitution at position 247 of a parent human IgG Fc region. Instead, at the page and paragraph cited by the Examiner (i.e., pages 52-53, paragraphs [0022]-[0024]), the Lazar et al. reference only discloses **glycine** and **valine** substitutions for the proline at position 247. Therefore, the Applicant respectfully submits that the Lazar et al. reference does not prove prior invention of the thing claimed and, thus cannot anticipate under 35 U.S.C. § 102.

In view of the foregoing, Applicant submits that the Lazar et al. reference cannot properly anticipate the presently claimed invention. Withdrawal of the present rejection under 35 U.S.C. 102(e) is believed to be in order, and is respectfully requested. If the Examiner persists with the rejection of the present claims under 35 U.S.C. § 102(e) as being anticipated by Lazar et al., Applicant kindly requests that the Examiner specifically point to

Serial No. 10/584,692
Docket No.: X16757

the page number and line number where the allegedly anticipating reference discloses a leucine or isoleucine substitution at position 247 of a human IgG Fc region.

It is believed that no fee is required for this response; however, the Commissioner hereby is authorized to charge any requisite fee for the response to Deposit Account No. 05-0840. The Examiner is encouraged to telephone the undersigned if it would be useful to expedite any aspect of the prosecution.

Respectfully submitted,

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